IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. MCNEIL-PPC, INC., a corporation, VERONICA CRUZ, and HAKAN ERDEMIR, individuals, Defendants.	Civil Action No. _____

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by its undersigned attorneys, respectfully states as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), to enjoin McNeil-PPC, Inc. ("McNeil"), a corporation, and Veronica Cruz and Hakan Erdemir, individuals (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and (b) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. § 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. McNeil is a New Jersey Corporation that manufactures, processes, packs, labels, holds, and distributes drugs, including over-the-counter ("OTC") drugs, through its unincorporated McNeil Consumer Healthcare Division, headquartered at 7050 Camp Hill Road, Fort Washington, Pennsylvania, within the jurisdiction of this Court. McNeil owns and/or operates through its Consumer Healthcare Division facilities in Fort Washington, Pennsylvania (the "Fort Washington Facility"), Las Piedras, Puerto Rico (the "Las Piedras Facility"), and Lancaster, Pennsylvania (the "Lancaster Facility").

5. Veronica Cruz is McNeil Consumer Healthcare Division's Vice President of Quality. Her responsibilities include establishing compliance priorities and strategies and overseeing the development of policies and requirements for quality systems. She has quality oversight of the Fort Washington, Las Piedras, and Lancaster Facilities. Ms. Cruz performs her duties primarily at McNeil Consumer Healthcare Division's headquarters located at 7050 Camp Hill Road, Fort Washington, Pennsylvania, within the jurisdiction of this Court.

6. Hakan Erdemir is McNeil Consumer Healthcare Division's Vice President of Operations, OTC Products. He oversees manufacturing, financial planning, contract manufacturing, strategic planning, facilities, and engineering groups at several McNeil facilities, including the Fort Washington, Las Piedras, and Lancaster Facilities. He is also responsible for determining when and what quantities of raw materials to purchase, and what products to produce. Mr. Erdemir performs his duties primarily at McNeil Consumer Healthcare Division's headquarters located at 7050 Camp Hill Road, Fort Washington, Pennsylvania, within the jurisdiction of this Court.

7. Defendants have been and are now engaged in the manufacture, processing, packing, labeling, holding, and distributing in interstate commerce various OTC drug products that are drugs within the meaning of 21 U.S.C. § 321(g).

8. Defendants regularly manufacture drugs using components they receive in interstate commerce and introduce finished drug products into interstate commerce for shipment outside Pennsylvania.

9. Inspections of the Fort Washington, Las Piedras, and Lancaster Facilities by the United States Food and Drug Administration ("FDA") have established that the drugs manufactured by Defendants at these facilities are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs and components are not in compliance with Current Good Manufacturing Practice ("CGMP") requirements for drugs, *see* 21 C.F.R. pts. 210 and 211.

10. Compliance with CGMP requirements ensures that drugs meet the safety requirements of the Act and have the identity and strength and meet the quality and purity characteristics that they purport or are represented to possess. FDA regulations, which establish minimum CGMP requirements applicable to human drugs, 21 C.F.R. pts. 210 and 211, require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured in order to prevent the production of unsafe and ineffective products. Drugs not manufactured, processed, packed, or held in conformance with CGMP requirements are deemed adulterated as a matter of law, without any showing of actual defect.

11. During FDA's most recent inspections of the Fort Washington, Las Piedras, and Lancaster Facilities, FDA investigators documented deviations from CGMP, including several deviations that were consistently found at multiple facilities.

12. Violations observed by FDA investigators during FDA's most recent inspection at the Fort Washington Facility from October 27 to December 9, 2010 include, but are not limited to, the following:

A. Failure to have adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a);

B. Failure to thoroughly investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed, and to extend the investigation to other batches of the same drug products and other products that may have been associated with the specific failure or discrepancy, as required by 21 C.F.R. § 211.192; and

C. Failure to establish an adequate Quality Control Unit having the responsibility for approving or rejecting all procedures or specifications affecting the identity, strength, quality, and purity of drug product, as required by 21 C.F.R. § 211.22(c).

13. Violations observed by FDA investigators during FDA's most recent inspection at the Las Piedras Facility from September 20 to November 2, 2010 include, but are not limited to, the following:

A. Failure to have adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a).

B. Failure to thoroughly investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed, and to extend the investigation to other batches of the same drug products and other products that may have been associated with the specific failure or discrepancy, as required by 21 C.F.R. § 211.192;

C. Failure to establish an adequate Quality Control Unit having the responsibility for approving or rejecting all procedures or specifications affecting the identity, strength, quality, and purity of drug product, as required by 21 C.F.R. § 211.22(c);

D. Failure to have or follow written procedures applicable to the Quality Control Unit, as required by 21 C.F.R. § 211.22(d); and

14. Violations observed by FDA investigators during FDA's most recent inspection at the Lancaster Facility from June 22 to July 9, 2010 include, but are not limited to, Defendants' failure to thoroughly investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed, and to extend the investigation to other batches of the same drug products and other products that may have been associated with the specific failure or discrepancy, as required by 21 C.F.R. § 211.192.

15. Defendants' deficient practices have resulted in numerous recalls of drugs manufactured in the Fort Washington and Las Piedras Facilities. On April 30, 2010, for example, McNeil's Consumer Healthcare Division recalled all lots of certain OTC liquid drugs, including children's Tylenol, Motrin, Zyrtec, and Benadryl products, because of manufacturing deficiencies. This recall has been described as one of the largest recalls of children's medications in history. Between January and October, 2010, McNeil initiated several recalls that affected a

variety of OTC drugs in tablet and caplet form, including Tylenol, Motrin, and Benadryl, after consumer complaints concerning musty or moldy odor were linked to the presence of a chemical called 2,4,6–tribromoanisole in McNeil's drugs.

16. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth above.

17. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce, as set forth above.

18. The CGMP deviations observed by FDA during the most recent inspections at the Fort Washington, Lancaster, and Las Piedras Facilities were similar to the deviations observed by FDA investigators during previous inspections of these facilities, including inspections of the Fort Washington Facility in April 2010 and the Las Piedras Facility from October 2009 to January 2010.

19. At the conclusion of each inspection, FDA investigators prepared and issued to representatives at Defendants' facilities detailed Lists of Inspectional Observations ("Forms FDA-483"), notifying them of the investigators' observations. The FDA investigators discussed the violations listed in the Form FDA-483s with McNeil representatives, who provided written responses to the Form FDA-483s and promised to correct the deficiencies observed by FDA. Nevertheless, FDA investigators have continued to observe similar CGMP violations at subsequent inspections.

20. Between 2009 and present, FDA representatives have participated in numerous meetings and teleconferences with McNeil officials, and representatives from McNeil's parent company, Johnson & Johnson, in order to convey the seriousness of the violations found by FDA investigators and FDA's belief that significant improvements are needed to bring McNeil's facilities into compliance with the law. Although McNeil has initiated a corrective action plan and made some improvements with respect to personnel and operations as a result of these meetings, recent FDA inspections have confirmed that violations persist and additional work is needed to fully address deficiencies and achieve sustained compliance with the law.

21. FDA also issued a Warning Letter to McNeil's Consumer Healthcare Division on January 15, 2010, identifying CGMP violations found during FDA's inspection of the Las Piedras Facility from October 2009 to January 2010. The Warning Letter, a copy of which was also sent to McNeil's parent company, Johnson & Johnson, emphasized the serious nature of the CGMP violations at the Las Piedras Facility and stated that failure to correct the violations could lead to regulatory action, including an injunction. The President of McNeil's Consumer Healthcare Division responded to the Warning Letter in writing on February 5, 2010, promising that corrective and preventative actions would be implemented to improve McNeil quality systems; however, as noted, sufficient corrections were not made.

22. Plaintiff is informed and believes that, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a) and (k), in the manner herein alleged.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants McNeil, Veronica Cruz, and Hakan Erdemir, and each and all of their directors, officers, agents, representatives, employees,

attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing articles of drug at or from the Fort Washington, Las Piedras, and Lancaster Facilities, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity with CGMP and the Act, in a manner that has been found acceptable by FDA;

II. Permanently restrain and enjoin Defendants McNeil, Veronica Cruz, and Hakan Erdemir, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and such other equitable relief as the Court deems just and proper.

DATED this 10th day of March, 2011.

Respectfully submitted,

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